

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/
FENFLURAMINE/DEXFENFLURAMINE)
PRODUCTS LIABILITY LITIGATION

MDL NO. 1203

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

CIVIL ACTION NO. 99-20593

v.

AMERICAN HOME PRODUCTS
CORPORATION

2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8425

Bartle, C.J.

March 11, 2010

Joseph A. Lagatutta ("Mr. Lagatutta" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In July, 2003, claimant submitted a second completed Green Form to the Trust signed by his attesting physician, John M. Cahill, M.D.³ Based on an echocardiogram dated

2. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

3. Mr. Lagatutta originally submitted a completed Green Form to the Trust in May, 2002 also signed by Dr. Cahill. Dr. Cahill attested in Part II of Mr. Lagatutta's original Green Form that claimant suffered from severe mitral regurgitation, pulmonary hypertension secondary to moderate or greater mitral regurgitation, an abnormal left atrial dimension, a reduced ejection fraction in the range of 50% to 60%, New York Heart Association Functional Class I symptoms, and had surgery to repair or replace his mitral and/or aortic valve(s) following the use of Pondimin® and/or Redux™. Dr. Cahill also attested that
(continued...)

October 18, 2000, Dr. Cahill attested in Part II of Mr. Lagatutta's Green Form that claimant suffered from severe mitral regurgitation⁴ and had surgery to repair or replace the aortic and/or mitral valve(s) following the use Pondimin[®] and/or Redux[™].⁵ Based on such findings, claimant would be entitled to Matrix A-1, Level III⁶ benefits in the amount of \$584,239.⁷

3. (...continued)
claimant suffered from mitral annular calcification ("MAC"), but stated: "mild; not the cause of his mitral valve dysfunction." Only claimant's July, 2003 Green Form is at issue in this claim.

4. Dr. Cahill also attested that claimant suffered from moderate aortic regurgitation. As Mr. Lagatutta's claim does not present any of the complicating factors necessary to receive Matrix Benefits for damage to his aortic valve, his level of aortic regurgitation is not relevant to this claim. See Settlement Agreement § IV.B.2.c.(2)(a).

5. In addition, Dr. Cahill attested that claimant suffered from pulmonary hypertension secondary to moderate or greater mitral regurgitation, an abnormal left atrial dimension, a reduced ejection fraction in the range of 50% to 60%, and New York Heart Association Functional Class I symptoms. These conditions, however, are not at issue in this claim.

6. In Part I of his Green Form, Mr. Lagatutta requested Matrix Benefits at Level IV. Upon review of claimant's Green Form and supporting materials, the Trust determined that claimant alleged conditions consistent only with a claim for Level III benefits. We agree. Based on the Green Form, Dr. Cahill did not identify conditions that qualify claimant for Level IV benefits. See Settlement Agreement § IV.B.2.c.(4).

7. Under the Settlement Agreement, a claimant is entitled to Level III benefits for damage to the aortic valve if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin[®] and/or Redux[™]." See Settlement Agreement § IV.B.2.c.(3)(a).

In the report of claimant's echocardiogram, Raymond N. Kawasaki, M.D., the reviewing cardiologist, determined that the study demonstrated MAC. Specifically, Dr. Kawasaki explained: "[m]itral annular calcification and sclerosis of the mitral leaflets."⁸ Dr. Cahill, however, attested in claimant's Green Form that Mr. Lagatutta did not suffer from MAC. Under the Settlement Agreement, the presence of MAC requires the payment of reduced Matrix Benefits. See id. § IV.B.2.d.(2)(c)ii)d). As the Trust does not contest Mr. Lagatutta's entitlement to Level III benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

In December, 2003, the Trust forwarded the claim for review by Kevin S. Wei, M.D., one of its auditing cardiologists. In audit, Dr. Wei concluded that there was no reasonable medical basis for Dr. Cahill's finding that claimant did not have MAC. In support of this conclusion, Dr. Wei explained that "MAC [is] clearly seen in [the] PLAX⁹ view" of claimant's echocardiogram.

8. Claimant's medical records also included reports drafted by Dr. Cahill from echocardiograms performed on May 14, 1998 and November 2, 2000. Regarding the May 14, 1998 echocardiogram, Dr. Cahill observed a "[c]alcified mitral annulus and sclerotic mitral valve that opens well." Regarding the November 2, 2000 echocardiogram, which was a transesophageal echocardiogram, Dr. Cahill commented that "[t]he mitral annulus shows very minimal calcification." In addition, claimant's medical records included the operative report from claimant's mitral valve replacement surgery, in which the surgeon, J. G. Ubatuba, M.D., noted that claimant's "[l]eaflets were severely calcified with short chordae tendinae making the valve incompetent."

9. "PLAX" refers to the parasternal long-axis view of an
(continued...)

Based on Dr. Wei's finding that claimant had MAC, the Trust issued a post-audit determination that Mr. Lagatutta was entitled only to Matrix B-1, Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.¹⁰ In contest, claimant submitted an April 8, 2004 letter from Dan J. Fintel, M.D., who stated, in pertinent part, that:

The minimal annular calcification noted in the Echocardiogram, in my opinion, played no role in the regurgitation problem seen in the Echocardiograms done on Mr. Lagatutta prior to his surgery In my opinion, the mitral annular calcification seen in Mr. Lagatutta was insignificant and did not cause any of the symptoms or findings which necessitated his valve being replaced. The mitral valve damage was wholly caused by the ingestion of Fen Phen and the replacement of the valve was not related in any way to the minimal mitral annular calcification noted

The echocardiogram tapes do not demonstrate, as suggested by Dr. Wei, that mitral annular calcification in any way played a role in the regurgitation seen. Absent that evidence, it would be medically inappropriate and unsupported to conclude that the regurgitation was caused by the minimal observed degree of mitral annular calcification noted.

9. (...continued)
echocardiogram.

10. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Lagatutta's claim.

Claimant argued, therefore, that he should prevail because it was his ingestion of Diet Drugs, not the presence of MAC, that required him to undergo surgery to replace his mitral valve.

The Trust then issued a final post-audit determination letter, again determining that Mr. Lagatutta was entitled only to Matrix B-1, Level III benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement.¹¹ See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Mr. Lagatutta's claim should be paid. On

11. The Trust argues that Dr. Fintel's letter should not be considered by the court both because it does not comply with Audit Rule 18(b), which states, in pertinent part, that "[c]ontest materials ... may include a verified statement of a medical expert," and because Mr. Lagatutta did not disclose Dr. Fintel's compensation or provide a list of cases in which he has served as an expert, Mr. Lagatutta included with his dispute of the final post-audit determination a Motion for Special Master to Grant Leave to Petitioner to File Supplemental Material for Purposes of the Show Cause Process, which again included Dr. Fintel's April 8, 2004 letter, a verification by Dr. Fintel, a curriculum vitae, a list of deposition and trial testimony, and a 2004 Fee Schedule. By its plain terms, Audit Rule 18(b) states that contest materials "may" include a verified statement. It does not, as the Trust contends, require that a verified statement be the only means by which a claimant may submit materials from a medical expert. Therefore, we will consider Dr. Fintel's letter in the form in which it was submitted in contest. Moreover, as we previously have stated, Rule 26(a)(2) disclosures are not required under the Audit Rules. See PTO No. 6996 (Feb. 26, 2007). Accordingly, claimant's Motion for Special Master to Grant Leave to Petitioner to File Supplemental Material for Purposes of the Show Cause Process is moot.

August 9, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 3817 (Aug. 9, 2004).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master.¹² The Trust submitted a reply on October 8, 2004. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

The issue presented for resolution of this claim is whether claimant has met his burden in proving that there is a reasonable medical basis for the attesting physician's finding that he did not have MAC. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of his claim, Mr. Lagatutta argues that he is entitled to Matrix A-1 benefits because his "minimal" MAC

12. Instead of responding to the Trust's statement of the case, claimant submitted a response to the Trust's Application to the court for issuance of an Order to show cause.

played no role in his valve replacement and should not be considered since there is a distinct medical difference between "minimal" MAC and MAC. According to Mr. Lagatutta, a reduction in Matrix Benefits based on a diagnosis of MAC is only justified when the defect in the mitral valve preexisted claimant's ingestion of Diet Drugs.

In response, the Trust argues that the Settlement Agreement is unambiguous that any amount of MAC requires the payment of Matrix Benefits at a reduced level, regardless of its severity or whether it required the mitral valve replacement.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, we reject Mr. Lagatutta's position that the level of MAC must be greater than minimal to justify a reduction in benefits. The Settlement Agreement specifically provides that a claimant will receive reduced Matrix Benefits for a mitral valve claim if he or she is diagnosed by echocardiogram with MAC. See Settlement Agreement § IV.B.2.d.(2)(c)ii)d). Although claimant relies on Dr. Fintel's opinion that his MAC was "minimal" and "insignificant," the Settlement Agreement provides that the presence of MAC, regardless of level, requires the payment of reduced Matrix Benefits. Unlike some of the other factors that reduce a claim to Matrix B-1, any presence of MAC, regardless of the amount, places the claim on Matrix B-1. Compare Settlement Agreement § IV.B.2.d.(2)(c)ii)d) with Settlement Agreement § IV.B.2.d.(2)(c)i)d) ("Aortic root dilatation > 5.0 cm").

Moreover, Mr. Lagatutta's reliance upon Dr. Fintel's opinion that the presence of MAC was not the medical cause of his mitral regurgitation or mitral valve replacement is misplaced. Causation is not at issue in resolving Mr. Lagatutta's claim for Matrix Benefits. Rather, claimant is required to show that he meets the objective criteria set forth in the Settlement Agreement. As we previously concluded:

Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which the qualification occurred

PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted:

... [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97. If claimants are not required to demonstrate causation, the converse also is true; namely, in applying the terms of the Settlement Agreement, the Trust does not need to establish that a reduction factor caused the regurgitation or valve replacement at issue. The Settlement Agreement clearly and unequivocally requires a claim to be reduced to Matrix B-1 if any amount of MAC is present. We must apply the Settlement Agreement as written. Accordingly, Dr. Fintel's opinion that claimant's

MAC was not the cause of his mitral regurgitation or valve replacement is irrelevant.¹³

For the foregoing reasons, we conclude that claimant has not met his burden in proving that there is a reasonable medical basis for finding that he did not have MAC. Therefore, we will affirm the Trust's denial of Mr. Lagatutta claim for Matrix A-1 benefits.

13. In any event, claimant fails to address the observation by Dr. Kawasaki, the cardiologist who reviewed claimant's echocardiogram of attestation, that claimant's MAC was concomitant to the mitral regurgitation. Claimant also does not address the conclusion by Dr. Ubatuba, who performed claimant's mitral valve replacement surgery, that the mitral valve was incompetent as a result of severe calcification.